DETAILED ACTION

This office action is a response to Applicant's amendment submitted September 12, 2011, wherein claims 1-28 are cancelled and claims 29, 31, 33, 34-36, and 38 are amended. Claims 29-38 are pending and are examined on the merits herein.

In view of the cancellation of claims 8 and 21-28, all rejections made with respect to those claims in the previous office action are withdrawn.

The following rejection of record is maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendment submitted April 28, 2011 introduced new claims 21-38, which limit original claim 8 drawn to administration of ribose to a mammal suffering from sepsis. Applicant indicated that support for the new claims could be found in the original claims and on page 24 of the specification. The original claims recite dosage forms, dosages, and routes of administration for reducing the recovery time of a mammal undergoing general anaesthesia, but do not

recite those details for enhancing the recovery from sepsis. Page 24 of the specification states that ribose administration can be used as an adjunct to usual therapies for sepsis, but page 24 provides no details about dosage, etc. for treatment of sepsis. The detailed information with respect to dosage and timing of administration of ribose as recited in the new claims is given in the specification specifically for recovery after general anaesthesia, as mentioned on pages 1-23 of the specification. Page 24 of the specification mentions sepsis independently of general anaesthesia, and recites the use of ribose in cases where antibiotic therapy has failed, but does not recite concurrent treatment with antibiotic and ribose. The examiner was unable to locate any recitation in the specification to indicate that the same detailed dosage information useful for recovery after general anaesthesia would be the same for recovery from sepsis. Thus, the skilled artisan would not be apprised that Applicant had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

Response to Arguments

Applicant argues that the amended claims recite treatment of a mammal in and/or released from intensive care, which is supported by the specification. The specification does give dosages for treatment of patients in and/or released from intensive care, but the specification does not give dosages for treatment of sepsis in any patient. Applicant argues that the specification discloses ribose administration as an adjunct to usual therapies for sepsis, and antibiotic treatment is one of those usual therapies. The specification discloses "if infection is not controllable by antibiotic therapy," but does not disclose that antibiotics are the “usual therapies” which might

benefit from addition of ribose. The claimed elements of treating sepsis using the dosages recited in the specification for other purposes and for combining antibiotics and ribose for treatment of sepsis might be *obvious* to the skilled artisan in view of the disclosure's teaching, but the disclosure does not actually teach them. For this reason, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over St. Cyr et al. (US 6,159,942, December 12, 2000, PTO-1449) in view of St. Cyr et al. (US 6,218,366, April 17, 2001, PTO-1449), Taylor et al. (Am J Physiol Lung Cell Mol

Physiol 275:L139-L144, 1998 as applied to claims 23-28 above, and Cunha (Med Clin North Am. 1995 May; 79(3):551-8, abstract only).

St. Cyr '942 teaches oral administration of ribose [column 3, line 16] to a subject suffering from sepsis [column 3, lines 43-46]. The preferred dosage is 1-20 or 4-8 grams per day, given 1, 2, or 3 times throughout the day [column 4, lines 39-57]. Ribose was also given to a patient who had been in the intensive care unit as a result of an extensive bacterial infection [column 9, Example 6].

St. Cyr '366 teaches administration of ribose to subjects experiencing a hypoxic condition [see abstract]. The ribose can be administered orally, intravenously, or intraperitoneally [claim 9] at a dosage of 1-60 grams [claim 3]. In one example, 10% ribose was administered intravenously with 5% glucose [column 10, lines 54-60].

Taylor teaches that tissue hypoxia is likely to occur during sepsis [page L139, second column, second paragraph].

Cunha teaches that antibiotic therapy is critical to treatment of the septicemic patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat sepsis in a patient in and/or released from an ICU using ribose and an antibiotic. St. Cyr '942 and '366 teach administration of ribose to treat sepsis and hypoxic conditions, including to ICU patients. Hypoxia is likely to occur during sepsis, as taught by Taylor. Thus, the skilled artisan would use ribose to treat sepsis and hypoxia which would likely occur with the sepsis. Antibiotics are commonly used to treat sepsis. The skilled artisan would treat sepsis using antibiotics and ribose

because both are known for treating sepsis. The use of ribose would have the added benefit of treating hypoxia, a complication of sepsis.

Response to Arguments

Applicant argues that St. Cyr '366 teaches administration of ribose for raising the hypoxic threshold in mammals experiencing a hypoxic condition, not for the treatment of an underlying condition. This argument is not persuasive because St. Cyr '942 teaches administration of ribose for sepsis (the underlying condition) and Taylor teaches that hypoxia is likely to occur during sepsis. The skilled artisan would administer ribose to treat the hypoxia and/or to treat the sepsis.

Applicant argues that Cunha teaches away from administration of other agents with antibiotics to treat sepsis because Cunha teaches that monotherapy is usually sufficient and that corticosteroids and mediator therapy have no place in the treatment of the septic patient. This argument is not persuasive because Cunha teaches that monotherapy is usually sufficient, but not always, and Cunha does not teach that *ribose* has no place in the treatment of the septic patient. Furthermore, St. Cyr '942 teaches ribose for the treatment of sepsis and St. Cyr '366 teaches ribose for the treatment of hypoxia, a complication of sepsis.

For these reasons, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,218,366 in view of Taylor et al. (Am J Physiol Lung Cell Mol Physiol 275:L139-L144, 1998), and further in view of Cunha (Med Clin North Am. 1995 May; 79(3):551-8, abstract only.

The '366 patent claims administration of ribose to increase tolerance to hypoxia in a subject, but does not claim administration to a patient suffering from sepsis. Taylor teaches that tissue hypoxia is likely to occur during sepsis [page L139, second column, second paragraph]. Thus, it would have been obvious to treat patients undergoing hypoxia due to sepsis. Cunha teaches that antibiotic therapy is critical to treatment of the septicemic patient. Thus, the skilled artisan would administer antibiotics to the subject suffering from sepsis because antibiotics are used to treat that condition. The '366 patent claims oral or intravenous administration at a dosage of 1-60 grams. The skilled artisan would use this guidance to optimize the dosage of ribose.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Primary Examiner, Art Unit 1623